

**Amendment and Response**

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Serial No.: 10/579,090

Confirmation No.: 5257

Filed: April 11, 2007

For: DNA SEQUENCE AND EXPRESSED RECOMBINANT GLYCOPROTEINS RELATED TO FELINE THYROTROPIN

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**Remarks**

The Office Action mailed January 5, 2009, has been received and reviewed. Claims 2, 3, 9, 13, 34, 37, 59, 61-63, 65, 70, 72-75, 77, 79, 81-83, and 86 having been amended, claims 1, 4-8, 10-12, 14-33, 39-58, 64, 66-69, 71, 76, and 84 having been canceled, without prejudice, and claims 87-98 having been added, the pending claims are claims 2, 3, 9, 13, 34-38, 59-63, 65, 70, 72-75, 77-83, and 85-98. Claims 9, 13, 34-38, 62, 63, 65, 73-75, 77-80, and 86 being withdrawn from examination as drawn to nonelected inventions, claims 2, 3, 59, 60, 61, 70, 72, 81-83, 85 and 87-90 are currently under examination. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the new and amended claims is found throughout the specification. Support for amended claim 82 is found, for example, on page 30, line 28 of the specification. Support for new claim 87 is found, for example, on page 24, lines 6-9 of the specification; support for new claims 88-90 is found, for example, on page 32, lines 4-10 of the specification; support for new claim 91 is found, for example, on page 8, lines 20-25 of the specification; support for new claims 92 and 93 is found, for example, on page 12, line 15 of the specification; support for new claim 94 is found, for example, in original claim 25; support for new claims 95 is found, for example, in original claim 29; support for new claims 96 and 97 is found, for example, in original claims 14-16, 20, and 21; and support for new claim 98 is found, for example, on page 15, line 15 of the specification.

**Continued Traverse of Restriction Requirement**

Applicants continue to traverse the Restriction Requirement. Applicants submit that all of pending claims 2, 3, 9, 13, 34-38, 59-63, 65, 70, 72-75, 77-83, and 85-98 share a single inventive concept under PCT Rule 13.1. Applicants submit that all pending claims comprise SEQ ID NO:1 and thus, all pending claims possess the same special technical feature.

Applicants request the rejoinder and examination of claims 2, 3, 9, 13, 34-38, 59-63, 65, 70, 72-

75, 77-83, and 85-98.

Applicants that pending claims 2, 3, 9, 13, 37, 38, 59-63, 65, 70, 72-75, 77-83, and 85, as amended, and new claims 87-92 and 98 all read on the elected species, a thyrotropin  $\beta$  subunit. Applicants submit that as amended, withdrawn claims 9, 13, 37, 38, 62, 63, 65, 73-75, and 77-80 read on a thyrotropin  $\beta$  subunit having SEQ ID NO:1, and thus, all read on the elected species presently under examination (thyrotropin  $\beta$  subunit). Thus, Applicants submit that the examination of all of the pending claims is proper and that the withdrawal of claims 9, 13, 37, 38, 62, 63, 65, 73-75, and 77-80, as amended, from examination, is improper.

Further, Applicants submit that with the withdrawn of claims 9, 13, 37, 38, 62, 63, 65, 73-75, and 77-80 from examination, the Examiner has improperly required restriction between combination and subcombination inventions. The examination of claims 2, 3, 9, 13, 37, 38, 59-63, 65, 70, 72-75, 77-83, 85, and 87-92 is respectfully requested.

Further, Applicants request the rejoinder and allowance of claims 34-36 and 86, all drawn to methods of using the polypeptides of claim 70.

### **Objection to Disclosure**

The disclosure is objected to because of informalities as listed on page 5 of the Office Action mailed January 5, 2009. This objection is traversed.

As recommended by the Examiner, the title of the invention has been amended to recite "RECOMBINANT GLYCOPROTEINS RELATED TO FELINE THYROTROPIN." In view of this amendment, Applicants submit that the objection to the title of the invention is moot.

Likewise, Applicants submit that the objection to page 50, line 7 of the specification is moot in view of the amendment of the specification to include a period at the end of the sentence ending on line 7 of page 50.

The Examiner objected to page 40 of the specification, asserting that statements made on page 40, lines 30-34 of the specification are inconsistent with statements made in Rayalam et al.

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(Domestic Animal Endocrinology 30:203-217, 2006). Applicant do not understand. Further, Applicants respectfully submit that it is inappropriate for the Examiner to request that the specification be edited in view of information that published after the filing date of the present application; doing so would potentially introduce new matter into the specification. The reconsideration and withdrawal of this objection is requested.

In view of the above discussion, reconsideration and withdrawal of the objection to the specification is requested.

**Objection to Claims**

Claims 2, 59 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. As requested by the Examiner, claims 2, and 59 have been amended to independent format and are drawn to "[a]n isolated feline thyrotropin  $\beta$ -subunit polypeptide, wherein the amino acid sequence consists essentially of SEQ ID NO: 1" (claim 2) and "[a]n isolated feline thyrotropin  $\beta$ -subunit polypeptide, wherein the amino acid sequence comprises SEQ ID NO: 1" (claim 59). The allowance of independent claims 2 and 59, and dependent claim 60 (which depends from claim 59) is requested. Likewise, the allowance of claims 3, 61-63, 65, and 90-97, all of which depend from independent claims 2 or 59, is requested. Likewise the allowance of independent claim 13 (drawn to "[a]n isolated feline thyrotropin yoked polypeptide . . . comprising a first polypeptide comprising SEQ ID NO: 1") and independent 70 (drawn to "[a]n isolated polypeptide comprising the amino acid sequence SEQ ID NO: 1") and dependent claims 9, 37, 38, 72-75, 77-83, 85, and 87-97 is requested.

**The 35 U.S.C. §112, First Paragraph, Enablement Rejection**

The Examiner has rejected claims 3, 61, 70, 72, 81-83, and 85 under 35 U.S.C. §112, first paragraph, alleging the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate

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in scope with these claims. This rejection is respectfully traversed. However, Applicants submit that this rejection is moot in view of the claim amendments, amendments presented to expedite prosecution. Applicants reserve the right to continue the prosecution of any cancelled subject matter in a continuing application. The reconsideration and withdrawal of this rejection is requested.

Further, Applicants submit that new claim 98, drawn to "[a]n isolated polypeptide comprising an amino acid sequence with at least 99% identity to SEQ ID NO:1," is enabled by the specification. The Examiner asserted that "claims . . . which recite 'at least 99% identity to SEQ ID NO:1' (which only tolerates a single amino acid change in SEQ ID NO:1) lack enablement in the absence of a functional limitation. This is because the art teaches that even single amino acid changes can drastically alter protein functionality and the specification does not teach how to use non-functional variants of SEQ ID NO:1" (page 11 Office Action mailed January 5, 2009). Applicants respectfully disagree, Claim 98 encompasses polypeptides with at most one amino acid change in the total 118 amino acid sequence of SEQ ID NO:1. Applicants submit that it is well known to the skilled artisan that the overwhelming majority of the polypeptides encompassed by claim 98 would demonstrate the same function as the polypeptide of SEQ ID NO:1. The specification provides guidance to one of the skill in the art to identify functional and nonfunctional polypeptides without undue experimentation. See, for example, page 37, line 17 to page 38, line 6 and Example 8 (page 48, line 26 to page 50, line 7) of the specification. Pursuant to MPEP 2164.08(b), [t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments . . . would be inoperative or operative with expenditure of no more effort than is normally required in the art." Applicants submit that the presence of inoperative embodiments within the scope of a claim 98 does not render the claim nonenabled, as the specification provides guidance to allow one of skill in the art to identify nonfunctional, inoperative embodiments without undue experimentation.

**The 35 U.S.C. §112, First Paragraph, Written Description Rejection**

The Examiner has rejected claims 3, 61, 70, 72, 81-83, and 85 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed. However, Applicants submit that this rejection is moot in view of the amendment of claims; amendments presented to expedite prosecution. Applicants reserve the right to continue the prosecution of any cancelled subject matter in a continuing application. The reconsideration and withdrawal of this rejection is requested.

Further, Applicants submit that the specification provides adequate written description for new claim 98, drawn to "[a]n isolated polypeptide comprising an amino acid sequence with at least 99% identity to SEQ ID NO:1." Claim 98 encompasses polypeptides with at most one amino acid change in the total 118 amino acid sequence of SEQ ID NO:1. With the written description requirement there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification (see MPEP § 2163). The specification teaches SEQ ID NO:1 and teaches amino acid substitutions for SEQ ID NO:1 (see, for example, page 14, lines 7-30 of the specification). While it might be a lengthy list, one of skill in the art, using the teachings of the specification combined with information that is well known in the art, can exemplify the claimed polypeptides, polypeptides with at least 99% identity to SEQ ID NO:1. Thus, the specification provides adequate written description for the polypeptides of claim 98.

**The 35 U.S.C. §112, First Paragraph, New Matter Rejection**

The Examiner rejected claim 82 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter. This rejection is traversed. Applicants submit that the rejection of claim 82 is moot in view of the amendment of claims 82 to recite "[a] kit comprising the feline thyrotropin  $\beta$ -subunit

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polypeptide of claim 1 and a radioiodide." Support for amended claim 82 is found, for example, on page 30, line 28 of the specification. The reconsideration and withdrawal of this rejection is requested.

**The 35 U.S.C. §102 Rejection**

The Examiner has rejected claims 3, 61, 70, 72 and 81-83, and 85 under 35 U.S.C. 102(b) as being anticipated by Yang et al. (2000 Domestic Animal Endocrinology. 18:363-378). This rejection is respectfully traversed. According to MPEP § 2131 a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." As amended, claims 3, 61, 70, 81-83 and 85 are drawn to polypeptides comprising the amino acid sequence SEQ ID NO:1 and claim 72 is drawn to polypeptides comprising the amino acid sequence SEQ ID NO:2. Applicants submit that Yang et al. does not disclose such polypeptides. Further, claim 82 is drawn to a kit comprising a feline thyrotropin  $\beta$ -subunit polypeptide and a radioiodide. Applicants submit that Yang et al. does not disclose a radioiodide. Thus, the disclosure of Yang et al. does not set forth each and every element of claims 3, 61, 70, 72, 81-83, and 85. The reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) is respectfully requested.

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**Summary**

It is respectfully submitted that the pending claims 2, 3, 9, 13, 34-38, 59-63, 65, 70, 72-75, 77-83, and 85-98 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of April, 2009.

By: Sandy Truehart  
Name: Sandy Truehart

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